

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	)	
Bonnette, et al.	)	Examiner Rodriguez
Serial Number: Unassigned	)	Group Art Unit 3763
Filed: Unknown	)	<b>PRELIMINARY</b>
For: Thrombectomy Catheter	)	<b>AMENDMENT</b>
and System	)	

Assistant Commissioner for Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Please amend the above referenced patent application  
as follows.

Charge or credit any small business entity fees to  
Deposit Account 10-0230.

In the Title of the Invention

Amend the Title of the Invention throughout the application  
to read --THROMBECTOMY CATHETER AND SYSTEM--.

In the Specification

In the specification, abstract, and parts list, delete all occurrences of "crossflow" and insert in its place --cross stream--. A substitute specification, a substitute abstract, and a substitute parts list are attached, together with a marked-up copy for the Examiner's reference.

In the Claims

Cancel claims 1-20 and 22-45 subject to the filing of a divisional patent application.

Amend claim 21.

Add new claims 46-73.

21. (once amended) A catheter comprising:
- a. a first tube having a proximal end and a distal end;
  - b. a second tube having a proximal end and a distal end, said first tube residing within and extending along the length of said second tube;
  - c. a jet body at said distal end of said first tube, said jet body including a jet emanator;
  - d. at least one outflow orifice and at least one inflow orifice formed in said second tube adjacent to said distal end thereof; and,
  - e. said jet emanator located at least in part distal to said distal end of said second tube, and having at least one jet orifice directed [toward said outflow and inflow orifices] in a proximal direction toward said distal end of said second tube.

46. The catheter of claim 21, wherein said inflow orifice comprises the open end of said second tube.

47. The catheter of claim 21, wherein said jet emanator is formed at least in part in a shape selected from the group consisting of L-shaped, J-shaped, semi-toroidal, and toroidal.

48. The catheter of claim 47, wherein said at least one jet orifice is located at the extreme end of said jet emanator.

49. The catheter of claim 47, wherein said at least one jet orifice comprises a plurality of jet orifices.

50. The catheter of claim 21, further comprising an isolation balloon attached to said catheter.

51. The catheter of claim 21, further comprising an isolation filter attached to said catheter.

52. An elongated device for treatment of thrombus or other unwanted material in a vessel or cavity of a living body comprising:

- a. a proximal end and a distal end;
- b. high pressure tubular means for conveying pressurized fluid from said proximal end to said distal end;
- c. pressurized fluid connection means for connecting the proximal end of said high pressure tubular means to a source of pressurized fluid;
- d. jet emanator means with at least one jet orifice for directing at least one high velocity fluid jet in the vicinity of said distal end, said jet emanator means being attached to and in fluid communication with said high pressure tubular means;
- e. second tubular means for conveying fluid, said second tubular means having inflow means comprising an opening at the distal end;
- f. said jet emanator means located at least in part distal to said opening at the distal end of said second tubular means, at least one of said jet orifices directing at least one high velocity fluid jet into said opening at the distal end of said second tubular means;
- g. said inflow means oriented so that at least one high velocity fluid jet entrains and draws surrounding blood or other fluid from a body vessel or cavity through said inflow means and into said second tubular means, and creating

a region of elevated pressure in said second tubular means;

- h. outflow means in said second tubular means, located at said region of elevated pressure, said outflow means thereby providing for passage of fluid out from said second tubular means into a body vessel or cavity, creating one or more cross stream jets which provide force (normal and/or drag forces) which help to break thrombus or other unwanted material off the surface of a body vessel or cavity;
- i. one or more of said high velocity jet(s) act to break apart thrombus or other unwanted material which has been entrained by said high velocity jet(s); and,
- j. said high velocity jet(s), said inflow means, and said outflow means create a recirculation pattern so that fluid flows from said outflow means with radial flow vectors and circumferential and/or axial flow vectors to said inflow means and back into said second tubular means, thereby providing enhanced removal of thrombus or other unwanted material off the surface of a body vessel or cavity, and macerating the thrombus or other unwanted material by action of said high velocity jet(s).

53. The device of claim 52, wherein said jet emanator means is formed at least in part in a shape selected from the group consisting of L-shaped, J-shaped, semi-toroidal, and toroidal.

54. The device of claim 52, wherein said at least one jet orifice is located at the extreme end of said jet emanator means.

55. The device of claim 52, wherein said at least one jet orifice comprises a plurality of jet orifices.

56. The device of claim 52, further comprising an inwardly facing curved surface near said distal end of said second tubular means; said inwardly facing curved surface acting to assist guidewire passage and alignment at said distal end of said second tubular means.

57. The device of claim 52, further comprising isolation means for isolating the portion of the body vessel or cavity near said distal end of said elongated device.

58. The device of claim 52, wherein said second tubular means provides for removal of fluid and thrombus or other unwanted material debris from the body vessel or cavity.

59. The device of claim 58, wherein said at least one of said jet orifices directing at least one high velocity fluid jet into said opening at the distal end of said second tubular means causing sufficient pressure in said region of elevated pressure to drive a flow of fluid and thrombus or other unwanted material debris along said second tubular means for removal from the body.

60. The device of claim 52, wherein high pressure fluid is provided in the range of approximately 150 to 500 psi.

61. The device of claim 52, wherein high pressure fluid is provided in the range of approximately 500 to 2500 psi.

62. The device of claim 52, wherein high pressure fluid is provided in the range of approximately 2500 to 50000 psi.

63. The device of claim 52, wherein high pressure fluid in said jet emanator means is in the range of approximately 50 to 350 psi.

64. The device of claim 52, wherein high pressure fluid in said jet emanator means is in the range of approximately 350 to 850 psi.

65. The device of claim 52, wherein high pressure fluid in said jet emanator means is in the range of approximately 850 to 35000 psi.

66. The device of claim 52, wherein said high velocity jet(s) have maximum instantaneous centerline velocity of approximately 2,000 to 30,000 cm/s.

67. The device of claim 52, wherein said high velocity jet(s) have maximum instantaneous centerline velocity of approximately 7,000 to 20,000 cm/s.



68. A system for treatment of thrombus or other unwanted material in a vessel or cavity of a living body comprising:

- a. an elongated device having a proximal end and a distal end;
- b. high pressure tubular means forming part of said elongated device for conveying pressurized fluid from said proximal end to said distal end;
- c. pressurized fluid connection means located at said proximal end of said high pressure tubular means;
- d. pressurized fluid source means connected to said pressurized fluid connection means;
- e. jet emanator means with at least one jet orifice for directing at least one high velocity fluid jet in the vicinity of said distal end of said elongated device, said jet emanator means being attached to and in fluid communication with said high pressure tubular means;
- f. second tubular means forming part of said elongated device for conveying fluid, said second tubular means having inflow means comprising an opening at the distal end;
- g. said jet emanator means located at least in part distal to said opening at the distal end of said second tubular means, at least one of said jet orifices directing at least one high velocity fluid jet into said opening at the distal end of said second tubular means;

- h. said inflow means oriented so that at least one high velocity fluid jet entrains and draws surrounding blood or other fluid from a body vessel or cavity through said inflow means and into said second tubular means, and creating a region of elevated pressure in said second tubular means;
- i. outflow means in said second tubular means, located at said region of elevated pressure, said outflow means thereby providing for passage of fluid out from said second tubular means into a body vessel or cavity, creating one or more cross stream jets which provide force (normal and/or drag forces) which help to break thrombus or other unwanted material off the surface of a body vessel or cavity;
- j. one or more of said high velocity jet(s) act to break apart thrombus or other unwanted material which has been entrained by said high velocity jet(s); and,
- k. said high velocity jet(s) said inflow means, and said outflow means create a recirculation pattern so that fluid flows from said outflow means with radial flow vectors and circumferential and/or axial flow vectors to said inflow means and back into said second tubular means, thereby providing enhanced removal of thrombus or other unwanted material off the surface of a body vessel or cavity, and macerating the thrombus or other unwanted

material by action of said high velocity  
jet(s).

69. The system of claim 68, further comprising isolation means for isolating the portion of the body vessel or cavity near said distal end of said elongated device.

70. The system of claim 68, further comprising:

- a. isolation means attached to said elongated device; and,
- b. isolation means separate from said elongated device.

71. The system of claim 68, wherein said second tubular means provides for removal of fluid and thrombus or other unwanted material debris from the body vessel or cavity.

72. The system of claim 71, further comprising means to regulate the rate of removal of fluid and thrombus or other unwanted material debris from the body vessel or cavity.

73. The system of claim 68, further comprising means for removal of fluid and thrombus or other unwanted material debris from the body vessel or cavity.

REMARKS

Reconsideration in view of the foregoing amendments and following remarks is respectfully requested.

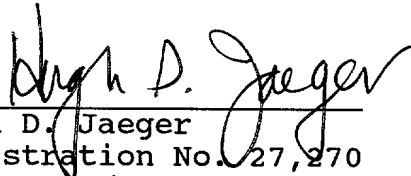
Claims 21 and 46-73 are drawn to a thrombectomy device and system. No new matter has been introduced.

If there are any further issues yet to be resolved to advance the prosecution of this patent application to issue, the Examiner is requested to telephone the undersigned counsel.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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CLEAN COPY OF CLAIM 21

21. A catheter comprising:
- a. a first tube having a proximal end and a distal end;
  - b. a second tube having a proximal end and a distal end, said first tube residing within and extending along the length of said second tube;
  - c. a jet body at said distal end of said first tube, said jet body including a jet emanator;
  - d. at least one outflow orifice and at least one inflow orifice formed in said second tube adjacent to said distal end thereof; and,
  - e. said jet emanator located at least in part distal to said distal end of said second tube, and having at least one jet orifice directed in a proximal direction toward said distal end of said second tube.